

**REMARKS UNDER 37 CFR § 1.111**

**Formal Matters**

Claims 1-13 and 17-20 and 35-42 are currently pending.

Claims 1-13 and 17-20 were examined. Claims 1-13 and 17-20 were rejected.

Applicant respectfully requests reconsideration of the application in view of the remarks made herein.

No new matter has been added.

**The Telephone Interview**

Applicant wishes to extend his appreciation to the Examiner for the courtesy provided to Applicant's representative during the telephone interview of January 18, 2008. During the Interview, the Examiner agreed that amending claim 17 to recited that said computer readable medium is not a carrier wave or signal per se, would overcome the rejection thereof under 35 USC Section 101. Regarding the remaining claims, Applicant's representative indicated that these claims should not be interpreted as judicial exceptions, and that therefore they should not be required to pass the "physical transformation" or "concrete, tangible and useful" tests. With regard to Singh et al. and Crosby et al., Applicant's representative discussed the features that are lacking in each, as noted with specificity below. For example, Applicant's representative noted that nowhere does Singh et al. disclose that the tumor samples contain normal tissue in the manner suggested by the Examiner. The Examiner indicated that he would further consider Applicant's arguments upon submission of this response.

This account is believed to be a complete and accurate summary of the interview as required by 37 C.F.R. § 1.133. If the Examiner believes that this summary is inaccurate or incomplete, Applicant respectfully requests that the Examiner point out any deficiencies in his next communication so that Applicant can amend or supplement the interview summary.

## **The Office Action**

### **Claims Rejected Under 35 U.S.C. Section 101**

In the Official Action of October 22, 2007, claim 17 was rejected under 35 U.S.C. Section 101 as being directed to non-statutory subject matter. The Examiner asserted that the claim is directed to a computer readable medium, which the Examiner interpreted to have statutory and non-statutory embodiments. The Examiner interpreted computer readable medium to include a carrier wave, directed to a signal per se that the Examiner interpreted to be non-statutory. In response thereto, Applicants have limited claim 17 by amending it above to recite that said computer readable medium is not a carrier wave or signal per se, as Applicant has not disclosed such an embodiment of a computer readable media and is now also clearly not claiming such an embodiment.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claim 17 under 35 U.S.C. Section 101 as being directed to non-statutory subject matter, as being inappropriate.

Although never explicitly rejecting claims 1-13 and 17-18 under 35 U.S.C. Section 101, the Examiner did assert that these claims are drawn to a process and that they do not require the production of a tangible result in a form that is useful to the user of the process or apparatus. The Examiner asserted that the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete and tangible result.

The USPTO Official Gazette Notice dated 22 November 2005, entitled “*Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility*” (“the OG Notice”) contains guidelines for patent examiners. Like the MPEP, the OG Notice does not have the full force and effect of law (see the OG Notice, Section I, second paragraph). This notwithstanding, review of these guidelines in the OG notice indicates that the Examiner’s remarks about claims 1-13 and 17-18 fail to comply with the guidelines provided in the OG Notice.

Section IV of the OG Notice explains, in detail, the procedures to be followed to determine whether a claimed invention complies with the subject matter eligibility requirement of 35 USC § 101. The only references to “tangible results” in this procedure appear under Step IV(C) – “*Determine Whether the Claimed Invention Falls Within Sec. 101 Judicial Exceptions – Laws of Nature, Natural Phenomena and Abstract Ideas.*” The first thing that Step IV(C) requires the Examiner to do is to “*determine whether [a claim] covers either a Sec. 101 judicial exception.*” Only if such a determination

is made, does the analysis then proceed to determine whether the claimed subject matter is nevertheless still patentable subject matter as a practical application of a Sec. 101 judicial exception. The claimed subject matter may nevertheless be patentable subject matter because, for example, (1) the claim provides a physical transformation (Step IV(C)(1)(a)); or (2) the claim produces a useful, concrete, and tangible result (Step IV(C)(1)(b)).

In the present Office Action, the Examiner did not attempt to determine whether any or all of claims 1-13 and 17-18 cover a Sec. 101 judicial exception (Law of Nature, Natural Phenomenon, or Abstract Idea). Rather, the Examiner concluded that claims 1-13 and 17-18 are drawn to a judicial exception with no analysis or explanation supporting this position. The Examiner then directly analyzed the criteria for a practical application of a Sec. 101 judicial exception. In this analysis, the Examiner stated that the claims and the process claimed need to either effect a physical transformation or produce useful, concrete and tangible results. Applying the criteria for a practical application of a Sec. 101 judicial exception to Applicant's claims without first establishing that Applicant's claims are drawn to a judicial exception amounts to a failure to comply with the above-referenced examination guidelines.

Applicant submits that none of claims 1-13 and 17-18 is drawn to a judicial exception because these claims do not cover a law of nature, natural phenomenon, or abstract idea. Claims 1-13 and 17-18 are directed toward analyzing characteristic signatures formed from tissue property values of a tissue , where the properties have been measured from a plurality of samples taken from a heterogeneous tissue region, and other non-abstract elements. It is clear that this method claimed by Applicant does not cover any law of nature or natural phenomenon. Further, it is clear from the above-recited elements of Applicant's claims, that claims 1-13 and 17-18 are not directed to an abstract idea, tissue properties of a tissue are real. Accordingly, the entire analysis as to where the claims "*provide physical transformation*" and/or "*produce a tangible result*" is not even pertinent under the above-referenced examination guidelines, because the claims are not directed to any Sec. 101 judicial exception in the first place. The Examiner's rejection under 35 U.S.C. §101 fails to comply with the examination guidelines and should be withdrawn on this ground.

Furthermore, even if any of the claims 1-13 and 17-18 were directed to a Sec. 101 judicial exception, which they are clearly not, the OG Notice defines "tangible" as being the opposite of "abstract." All that is required is that the claim must set forth a practical application to produce a real-world result. Here, the claims all are practical applications producing the real-world result of rank ordering characteristic signatures based on proximity to a trend profile to identify those tissue properties that are likely most related to a disease or other property of the tissues being studied. The claims all

include tangible and concrete elements of forming a plurality of characteristic signatures from values for tissue properties having been measured from a plurality of tissue samples. Further claim 2 recites an actual step of measuring a specific property of the samples, which is clearly a physical step. Likewise, claim 3 requires the provision of a heterogeneous tissue sample, which, it is respectfully submitted, clearly concrete and tangible. The taking of samples recited in claim 3 is also clearly a physical step. Still further, claim 4 recites measuring specific properties, which is tangible, real-world and concrete. Similarly, claim 12 recites measuring using a microarray technique, which is physical, tangible and useful.

Accordingly, for at least these three independent reasons, Applicant submits that claims 1-13 and 17-18 are all patentable under 35 U.S.C. § 101.

#### **Claims Rejected Under 35 U.S.C. Section 102(b) (Singh et al.)**

Claims 1-13 were rejected under 35 U.S.C. Section 102(b) as being anticipated by Singh et al. (“Gene expression correlates of clinical prostate cancer behavior”, Cancer Cell, Vol. 1, March 2002).

The Examiner asserted that “Singh et al. have taken normal prostate tissue that is bordered on two sides by diseased tissue and performed gene expression analysis and histological examinations resulting in a rank ordering of characteristic genes that can be used in the early diagnosis of prostate cancer.” The Examiner asserted that tissue used by Singh et al. “is viewed as a heterogeneous tissue region”, composed of two portions (Normal and Tumor). Applicant would agree that 65 of the 235 specimens described by Singh et al. had tumor on opposing sides of the tissue specimen, as disclosed by Singh et al. at page 204, column 1, second full paragraph. However, regarding these 65 specimens, Applicant does not find a disclosure by Singh et al. that the middles of these samples contain normal tissue. It is respectfully submitted that the Examiner’s assertion in this regard is speculation, and not supported by Singh et al. It is further respectfully submitted that the “Figure 1” on page 11 of the Office Action dated 10/22/2007 is not disclosed by Singh et al., was created by the Examiner, and is a result of pure speculation on the part of the Examiner. The mere fact that a tissue specimen has tumor on opposing side of the tissue specimen does not require that the center of the specimen be composed of normal tissue. Clearly the specimen may be composed entirely of tumor tissue, which Applicant respectfully submits is the more likely scenario.

Further, Singh et al. discloses that high quality expression profiles were successfully derived from 52 of the 65 prostate tumor specimens. Additionally, high quality expression profiles were

successfully derived from 50 nontumor prostate samples. The nontumor prostate samples are distinct from the prostate tumor samples and are treated as such. Genes were ranked according to their differential expression across the two classes (tumor versus normal). That is, the gene expression levels were analyzed for each of 52 different tumor samples and 50 different nontumor (normal) samples.

The Examiner indicated that a “plurality of cell properties” is interpreted to include the individual expression states of a plurality of genes, i.e. a cell property can be the expression state of a particular gene, and thus a “characteristic signature” was interpreted to be a particular profile of expression for a gene or subset of genes in the context of a particular cell or tissue type. Although Applicant does not necessarily agree with the Examiner’s reasoning, Applicant respectfully points out that the claims recited that each characteristic signature is formed of values for a particular property having been measured from a plurality of samples taken from a heterogeneous tissue region. It is respectfully submitted that nowhere does Singh et al. disclose that more than one sample is taken from any of the 52 prostate tumors or 50 nontumor samples.

Applicant respectfully submits that Singh et al. fails to disclose or inherently possess all features recited in independent claim 1. As Applicant has repeatedly noted previously, Singh et al. fails to disclose forming a plurality of characteristic signatures from measurements taken from samples taken from successive locations along a determined profile of locations through the heterogeneous tissue. The Examiner has speculated that Singh et al. discloses heterogeneous tissue, but this is unsupported by the disclosure of Singh et al. Further, even if Singh et al. did disclose a heterogeneous tissue sample, which Applicant respectfully submits that Singh et al. clearly does not, Singh et al. does not disclose taking a plurality of samples from a heterogeneous tissue region, or taking a plurality of samples from a heterogeneous region along a determined profile of locations through the heterogeneous tissue region.

For at least the above reasons, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1-13 under 35 U.S.C. Section 102(b) as being anticipated by Singh et al. (“Gene expression correlates of clinical prostate cancer behavior”, Cancer Cell, Vol. 1, March 2002), as being clearly inappropriate.

#### **Claims Rejected Under 35 U.S.C. Section 102(e) (Crosby et al.)**

Claims 1-10, 12-13 and 17-20 were rejected under 35 U.S.C. Section 102(e) as being anticipated by Crosby et al. (US Patent Application Publication No. 2003/0190689). In the Examiner’s “Response to Arguments” section on page 18 of the Office Action, the Examiner asserted that Crosby et al. teaches

obtaining a plurality of sample from patients having positive and negative disease outcomes [0025] and that this read on the plurality of samples recited in Applicant's claims. Applicant respectfully traverses. Applicant respectfully submits that the "plurality of samples" recited in the present claims are taken from a heterogeneous tissue region. Thus, a plurality of samples are taken from a single specimen at successive locations along a determined profile of locations through that single heterogeneous tissue region specimen. Crosby et al. fails to teach or suggest these features, as Crosby et al. merely discloses at paragraph [0025] that samples are taken from a plurality of patients. There is no teaching or suggestion of taking multiple samples along a determined location profile in a single heterogeneous tissue region of any one patient.

The Examiner further asserted that Crosby et al. teaches the analysis of multiple sequential slices at paragraph [0080] and interpreted this as a disclosure of "measuring from a plurality of samples taken from a heterogeneous region". Applicant respectfully traverses. Crosby et al. does not disclose that the slices are a plurality of samples "wherein the plurality of samples have been taken from successive locations along a predetermined profile of locations through the heterogeneous tissue region", or "at least one sample being taken from the second portion" that borders a first portion, as is currently claimed. Instead, Crosby et al. merely discloses the standard practice of slicing up tissue to analyze protein activity by slice. If cell having activated proteins are identified in a slice, these results can be directly compared to normal cells. However, Crosby et al. neither discloses nor suggests that the normal cells are sampled from any particular location, or even that the normal cells are cells from any of the slices, as they could be one or more control samples. Clearly Crosby et al. lacks any disclosure or suggestion of "forming a plurality of characteristic signatures, each said characteristic signature being formed of values for a particular property having been measured from a plurality of samples taken from a heterogeneous tissue region, wherein the heterogeneous tissue region includes a first portion having at least first and second types of tissue, bordered by a second portion, said second portion considered to be devoid of the second type of tissue, wherein the plurality of samples have been taken from successive locations along a determined profile of locations through the heterogeneous tissue region, with at least one sample being taken from the second portion, and wherein each of said characteristic signatures are formed from different ones of said particular properties, respectively".

Applicant respectfully submits that Crosby et al. fails to disclose or inherently possess all features recited in independent claims 1, 17 and 18. As noted by the Examiner, Crosby et al. obtains cellular samples from a plurality of patients (see paragraph [0025]). The biomarkers are then used to evaluate these samples. Crosby et al. does not disclose a plurality of samples being taken from

successive locations along a determined profile of locations through a heterogeneous tissue region. It therefore follows that Crosby et al. cannot form characteristic signatures based on such samples, or a trend profile.

For at least the above reasons, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1-10, 12-13 and 17-20 under 35 U.S.C. Section 102(e) as being anticipated by Crosby et al. (US Patent Application Publication No. 2003/0190689), as being clearly inappropriate.

### **New Claims**

New claims 35-36 have been presented above in response to the Examiner's indication that the recitation of a result of the process being outputted to a display, or to a user, or in a graphical format, or in a user readable format, or by including a result that is a physical transformation, would overcome any 35 USC Section 101 rejection as being nonstatutory.

New claims 37-39 depend from claims 1, 17 and 18, respectively, and further recite that the second type of tissue comprises diseased tissue. Support for these amendments can be found, for example, at paragraph [0044] and throughout the specification.

New claims 40-42 depend from claims 1, 17 and 18, respectively, and further recite that a plurality of samples are taken from said first portion. Support for these amendments can be found, for example, at Figs. 1-4 and the descriptions thereof.

It is respectfully submitted that new claims 35-42 are allowable over the art of record and indication of such allowance is respectfully requested in the next Official Action.

### **Conclusion**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

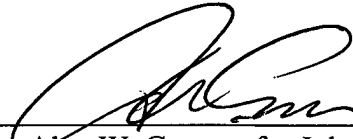
The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078, order number 10030215-1.

Respectfully submitted,

Date: \_\_\_\_\_

1/22/08

By: \_\_\_\_\_



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